K103744

MAY 12 2011

510K Summary

Prepared: Dec. 14, 2010

Submitted by: Quantimetrix Corporation

Establishment Address: Quantimetrix Corporation
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Redondo Beach CA 90278
Phone: 310/536-0006 FAX: 310/536-9977

Establishment Registration Number: 2020715
Contact Person: Kalyna Snylyk, Director of Quality Assurance & Regulatory Affairs
Proprietary Name: Dropper A1c Diabetes Control
Common Name: Hemoglobin A1c Control
Classification Name: Single (Specified) Analyte Quality Control Material (Assayed and Unassayed), (21 CFR 862.1660)
Product Code: JJX

Substantial Equivalence:

The Quantimetrix Dropper A1c Diabetes Control is supplied as a frozen liquid in two levels and consists of a human whole blood matrix containing preservatives to which reagent grade chemicals were added to chemically react with the hemoglobin to achieve the two levels.

The Quantimetrix controls are substantially equivalent to other such controls in general use, such as the MAS Diabetes Control, sold by Microgenics Corporation Inc., which is supplied liquid in two levels as a whole blood matrix with pure chemicals added by the manufacturer.

Assayed values are determined from in-house data.

Description:

Dropper A1c Controls are supplied in two levels, 4 bottles total, 2 x 2 mL each level per box. The controls are supplied as a ready-to-use frozen liquid, requiring no reconstitution or dilution. They are prepared in a whole blood matrix fortified to target levels with reagent grade chemicals added to achieve the two levels. Preservatives have been added to inhibit microbial growth.

Intended Use:

The Quantimetrix Dropper A1c Diabetes Control is intended for the quality control of laboratory procedures used to quantitate HbA1c.

Technological Characteristics Compared to Predicate Devices:

The Quantimetrix control product employs a similar matrix and constituent formulation to the equivalent predicate device listed above: whole blood matrix fortified with reagent grade chemicals as well as preservatives. The Quantimetrix Control also has similar storage and stability requirements as the equivalent devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MAY 12 2011

Quantimetrix Corporation
c/o Kalyna Snylyk
Director, Quality Assurance/Regulatory Affairs
2005 Manhattan Beach Blvd.
Redondo Beach, CA 90278

Re: k103744
Trade Name: Dropper A1c Diabetes Control
Regulation Number: 21 CFR § 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I, reserved
Product Code: JJX
Dated: December 17, 2010
Received: March 7, 2011

Dear Ms. Snylyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form.

510(k) Number (if known): K103744

Device Name: Dropper™ A1c Diabetes Control

Indications for Use:

The Quantimetrix Dropper A1c Diabetes Control is intended for the quality control of laboratory procedures used to quantitate HbA1c.

Prescription Use _X__ AND/OR Over-The-CounterUse ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K103744